DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region a1866d

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6008

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 05, 2001

File # 02-NWJ-04

Mr. James Liberi
President
LeFin L.L.C. T/A New Jersey Fisheries
300 Main Street
Maple Shade, NJ 08052

Dear Mr. Liberi:

We inspected your firm, located at 300 Main Street, Maple Shade, New Jersey on August 8 & 13, 2001 and found that you have serious deviations from the seafood hazard analysis critical control point (Seafood HACCP) regulations found in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention, cause your fresh Scombroid species fish (mahi-mahi, yellow fin tuna, bluefish) and pasteurized crabmeat to be in violation of section 402(a)(4) of the Federal Food Drug & Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). However, your firm has no written HACCP plan to address the food safety hazard of Clostridium Botulinum for the receipt and storage of pasteurized, refrigerated crabmeat. This deviation was previously brought to your attention in our letters of April 5, 1999 and August 30, 2000.

2. You must fully implement the record keeping and monitoring system listed in your HACCP plan in order to comply with 21 CFR 123.6(b). Your firm did not record monitoring observations at the receiving or storage critical control points (CCP's) in order to control the hazard of histamine production, as listed in your HACCP plan

for fresh bluefish, mahi-mahi and tuna. Your HACCP plan for these products provides for a monitoring record system. However, your firm has not implemented the record keeping system provided for in the plan. No monitoring records were available for review during our inspection on August 8 & 13, 2001. A similar deficiency was previously brought to your attention in our correspondence dated April 5, 1999.

3. You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR.123.6(c)(3). However, your HACCP plan for fresh Scombroid species fish (mahi-mahi, yellow fin tuna and bluefish) does not list adequate critical limits at the receiving and storage critical control points (CCP's). For example, your critical limit at the receiving CCP is listed as, "Thoroughly iced, not to exceed 45 ^{0}F". Scombroid species fish should be maintained at $\leq$ 40 ^{0}F throughout the transportation and receiving process. Temperature excursions above 40 ^{0}F must be evaluated for potential time/ temperature abuse and corrective actions must be taken, if warranted. Similarly, the critical limit at the storage CCP does not address adequacy of ice or other cooling media during product storage.

Note: *Please refer to the FDA Fish and Fisheries Product Hazards & Controls Guide, Third Edition, for recommended maximum critical limits, monitoring procedures and corrective actions.*

This letter may not list all deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/ or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a revised HACCP plan, revised monitoring procedures, copies of revised monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when the corrections will be completed.

Your response to this letter should be directed to the U.S. Food and Drug Administration, Attention: Richard D. Manney, Acting Compliance Officer at the address and telephone number listed above.

Sincerely,

Douglas I. Ellsworth
District Director
New Jersey District